

## Case Report

# Training with FES-assisted cycling in a subject with spinal cord injury: Psychological, physical and physiological considerations

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**Context:** People with spinal cord injury (SCI) experience the effects of a sedentary lifestyle very early on. Literature data suggest that programs using FES-assisted cycling would contribute to reduce the consequences of physical inactivity. The objective was to assess the feasibility of 12-month training on a FES-assisted bike of a subject with paraplegia for 21 years, T3, Asia Impairment Scale (AIS) A. An evaluation of morbidity, self-esteem, satisfaction, quality of life and duration of pedaling was performed. The impact on pain, cardiorespiratory function, body composition and bone metabolism were also assessed.

**Findings:** The acceptability score of the training constraints increased from 51 to 59/65 and satisfaction was high around 8/10. The pedaling duration increased from 1' to 26' on the recumbent bike and from 1' to 15' on open terrain. No significant changes were found with BMD and cardiorespiratory measures during exercise tests. SF 36 showed significant improvement of more than 10% and the Rosenberg Self Esteem score rapidly improved from 36 to 39/40. At the end of the training, the patient reached the objective of the Cybathlon 2016 by covering 750 m in less than 8 minutes, at an average speed of 5.80 km/hr.

**Conclusion/Clinical relevance:** A person with high and complete level of SCI for more than 20 years can undertake this type of challenge if the prerequisites are met; this training is without danger if the safety precautions are respected; the challenge of participating in a competition had a powerful impact on JP's self-esteem and perceived quality of life.

**Keywords:** Spinal cord injury, Functional electrical stimulation, Muscle, Cycling, Quality of life

## Context

People with spinal cord injury (SCI) experience the physical and psychological effects of immobility and a sedentary lifestyle very early on. Training programs are crucial to reduce the consequences of physical inactivity.<sup>1-4</sup>

In recent years, several innovative techniques have been developed to train the mobility of the lower limbs in SCI rehabilitation programs such as functional electrical stimulation (FES). Cycle ergometers can be motorized and thus offer only passive mobilization. Yet if the motorized function is turned off, applying FES to the glutei, quadriceps and hamstrings makes it possible to reproduce pedaling movements to which

resistance can be applied. Studies have indeed suggested the promising effects on body composition and bone remodeling especially when training begins early, lasts sufficiently long and is conducted at high intensity.<sup>5,6</sup> The cardiovascular benefit has been suggested by the increase in VO<sub>2</sub>max and the drop in low-density lipoprotein (LDL) cholesterol.<sup>7,8</sup> In one study, 4 weeks of training was enough to increase muscle volume as reflected by changes in the muscle cross-sectional area, from a minimum of 15–17% for some muscles and a maximum of 25% for others.<sup>9</sup>

The main objective of the present study was to assess the physical, psychological and functional feasibility of training a patient with paraplegia on a FES-assisted recumbent bike – initially fixed on a stationary stand and then outdoors. The secondary objectives were to

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**Table 1** Schedule for the muscle training program.

Inclusion	Clinical examination / venous Doppler ultrasound of lower limbs / exercise test / mapping of sublesional muscles for electrical stimulation
1st to 6th month	Home electrostimulation (isometric mode): Two to three 30-minute sessions per week using the <b>Cephar Physio 4®</b> with 4 cables: Parameters: rectangular currents with rising ramp, frequency: 30 Hz, pulse duration: 300 µs, stimulation trains: 10 s and rest time: 3 s Repartition of electrodes: - <b>month 1</b> : right and left rectus femoris, right and left biceps femoris (surface electrodes: 5 × 5 cm) - <b>months 2 to 6</b> : right and left quadriceps (rectus femori, vastus lateralis and vastus medialis), right and left hamstrings (biceps femoris, semi-membranous, semi-tendinous) (larger surface electrodes: 4.5 × 10 cm)
7th to 11th month	FES on stationary recumbent bike <b>Berkelbike Pro®</b> then on a non-stationary bike ( <b>Ice Trike Adventure®</b> ): Two to three 30-minute sessions per week with the <b>Berkelbike FES Box®</b> with 6 cables. Parameters: rectangular currents with rising ramp, frequency: 30 Hz, pulse duration: 300 µs, stimulation trains: 10 s. Maximal intensity: 150 mA A 10 to 15 minutes warm-up stimulation session at a 20 Hz frequency was performed before each training session. Repartition of electrodes: - 2 large electrodes for the right and left quadriceps (1 for rectus femori + vastus lateralis and 1 for vastus medialis) - 1 large electrode for the right and left hamstrings
12th month	Cyathlon competition

assess (1) the impact of this type of training on pain, cardiorespiratory function, muscle atrophy, body composition and bone metabolism and (2) the medical-technical requirements in order to personalize the adaptations of the stimulation patterns and use of the recumbent bike in a standardized outdoor environment. This study was driven by the subject's preparation for an international competition in cycling + FES (Cyathlon, Zurich 2016).

## Case report

### Participant

Mr JP, 47 years old had paraplegia for 21 years T3, Asia Impairment Scale (AIS) A with no zone of partial preservation. He had a sacral pressure injury treated with a musculocutaneous flap taken from the gluteus maximus and a right ischial pressure injury that lasted several months before healing completely a few days before study inclusion. He presented spasms in the lower limbs spreading to the abdomen. His Body Mass Index (BMI) was estimated at 23 (height 178 cm and weight 74 kg). A prior venous Doppler ultrasound of the lower limbs was normal. The initial T-score with DXA was estimated to be -1.6. He never used FES prior to his inclusion.

**Training** began with a home FES program (Table 1). At the start of each month, mapping determined the intensity of electrical stimulation needed to achieve a maximum contraction level i.e 4/5 MRC (Medical Research Council) Scale. An FES program on a training bike using first a stationary indoor bike and then a non-stationary outdoor bike was then conducted Fig 1. The stationary recumbent bike was the **Berkelbike Pro®** used without any adaptation. The competition bike was the

**ICE Trike Adventure 26®**, selected because it lends itself more easily to technical adaptations. In both bikes, the electrostimulator was a **Berkelbike FES Box®**. The stimulation at the start of training was a generic pattern provided by the stimulator and designed to be adjusted in order to optimize pedaling performance, provide smooth and regular pedaling, and reduce fatigability. The subject can directly adjust the stimulation intensity delivered to the muscles, via the FES stimulation box interface. We have modified the pattern to optimize the pedaling of our patient (Fig 1). To minimize fatigue, stimulation during extension phase was firstly distributed over both the vastus lateralis and rectus femori, then to the vastus medialis. Two speedometers were set up (one visible to a person walking aside the trike and one with the screen oriented towards JP). As a result, the participant was able to adjust himself the intensity of FES on the basis of a single data: the cadence (number of pedal revolutions per min). Optimal cadence (47 rpm) instructions were delivered, based on the best efficiency reported by literature data<sup>10</sup> and corresponding to the minimum speed required to reach the main selection criteria (750 m in under 8 minutes). Stimulation was manually adjusted by the participant when the speed went below 5.6 km/h (=47 rpm crank cadence). Finally, training was considered as a whole and included the 6 month period of isometric stimulation of the sublesional muscles and the 6 month period of FES cycling, on a stationary, then on a competition bike.

### Data analysis

As this study was designed as a single case report, the statistical analysis was applied on repeated measures




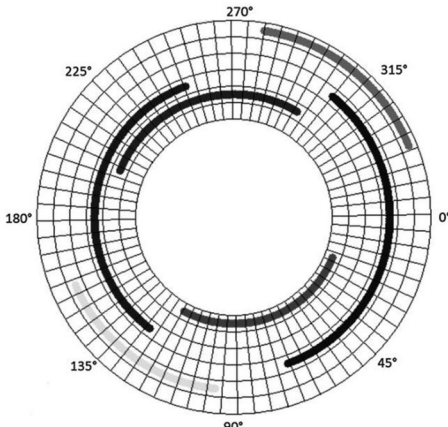
	Berkelbike Pro®	Ice Trike Adventure®
		
	Training indoor bike	Training outdoor bike/ Competition bike
Length	160-180 cm	165-213 cm
Width	77-79 cm	80-82.5 cm
Height	90-110 cm	75-80 cm
Frame material	Aluminum	Steel
Weight	21 kg - 46 pounds	16.5 Kg – 36.2 pounds
Tires	2 back tires (20") and 1 front tire (16")	2 front tires (24") and 1 back tire (24")
Propelling mode	Arm propelling Control handle of the front guide wheel above and ahead Leg propelling (in combination with FES)	No arm propelling Control handle of the front guide wheels on the sides Leg propelling (in combination with FES)
Others characteristics	Seated position on the bike	Semi recumbent position A full range of vision Folding handle and bike More accessible for wheelchair–bike transfers
Price	4800 € (5700 USD)	3000 € (3600 USD)
FES program	<div>On each leg, one channel is dedicated to the Vastus lateralis + Rectus Femoris muscles, a second channel to the Vastus medialis and a third one to the hamstrings.</div> 	
Final stimulation pattern	<div>Berkelbike FES Box®</div> <div><div></div> LEFT RECT. FEM. &amp; VAST. LAT.</div> <div><div></div> LEFT VAST. MEDIAL.</div> <div><div></div> LEFT HAMSTRINGS</div> <div><div></div> RIGHT RECT. FEM. &amp; VAST. LAT.</div> <div><div></div> RIGHT VAST. MEDIAL.</div> <div><div></div> RIGHT HAMSTRINGS</div> 	

Figure 1 Training and competition bikes & Placement of surface electrodes and final FES pattern.

recorded weekly before and after the Cybathlon competition. They provided monthly replicates data. Those recorded in the end were regrouped with the last month measurement in a total of four months of preparatory training (M1, M2, M3 and M4 + END). For the few missing records, the average of the repeated

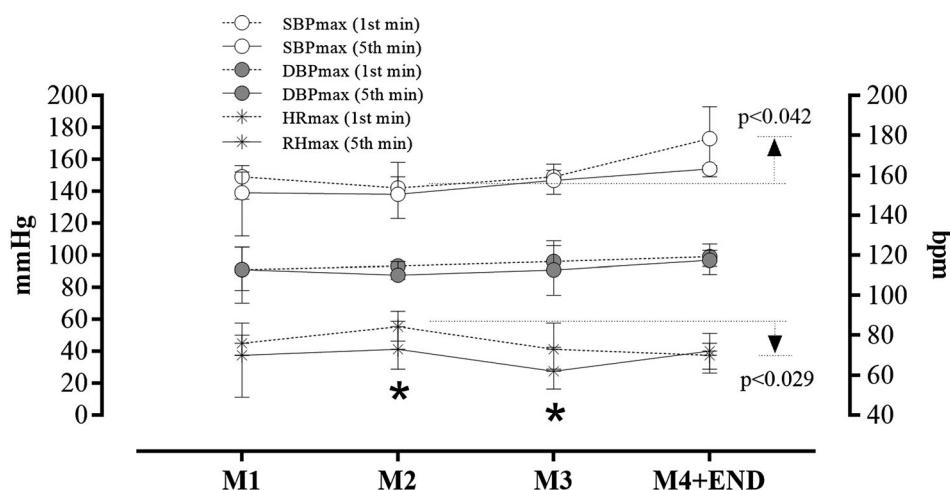
recordings was used to complete data set, enabling the application of a statistical test for repeated measures. Non-Gaussian distribution was observed among some data. As a result, non-parametric tests were used. The Friedman test for repeated measures followed by Dunn’s multiple comparisons were used to detect

**Table 2 Tolerance data and cycling performances.**

	W1	W2	W3	W4	W5	M1	W6	W7	W8	W9	W10	M2	W11	W12	W13	W14	M3	W15	W16	W17	W18	W19	M4	W20	W21	W22	END	...	W29	
Number of sessions in the week	3	2	2	2	1		2	2	2	2	No training		1	1	2	2		No training	2	4	No training	3		3	3	CYBA THLON		2	1	
Training modalities	SB	SB	SB	SB	SB		SB	SB	SB	SB			SB + CB	SB	SB	SB			SB + CB	SB + CB		SB + CB		SB + CB	SB			HT	CB	
Pain evaluation (VAS) 0 to 10	0	0	0	0	0		2	2	0	0			nc	0	0	0			0	0		5		4	nc	0				
Rating of perceived effort (Borg score from 6 to 20)	10	11	15	10	11		9	11	9	11			nc	13	9	9			9	9		12		11	nc	7				
Acceptability of constraints scale /65 (see <a href="#">appendix</a> )						51						55					56						59				59			
Evaluation of satisfaction 0 to 10*						8						8					6						8				10			
Longest duration of pedaling on SB (sec)	255	190	200	181	72		313	286	228	148			77	235	322	223			160	217			415		1549	1556	750 m under 8 min			
Longest distance covered on SB (m)							690	620	400	240			137	230	300	300				150			480		1820	1580				
Longest duration of pedaling on CB (sec)													85						223	454			386		914				824	
Longest distance covered on CB (m)													120						150	550			340		760				1080	

W, week; VAS, visual analog scale; nc, unknown; SB, stationary bike; CB, competition bike; HT, home training.

\*In response to the question: "How satisfied were you with your training experience last month? (0: not at all satisfied to 10: completely satisfied).



**Figure 2** Hemodynamic performance represented by superimposed points graph linking points in time with data grouped by variables during the 1<sup>st</sup> and the 5<sup>th</sup> minutes on training session (legend). X axis presents the set of repeated measures recorded weekly during the first (M1), second (M2), third (M3) and fourth (M4) months before competition including the records in the end of training added in the M4 time-point (M4 + END). The heart rate (HR) calculated by beat per minutes (bpm) is linked to right Y axis whereas the systolic (SBP) and diastolic (DBP) blood pressure are linked to left Y axis. The arrow bounded by pointed lines indicates a significant difference ( $p < 0.05$ ) between M2 and M4 + END only detected for SBP and HR. The asterisk (\*) indicated significant differences ( $p < 0.05$ ) between the 1<sup>st</sup> and the 5<sup>th</sup> minutes on training session for each point in time.

significant changes between different points in time (M1, M2, M3 and M4 + END) for the set of measures weekly recorded.

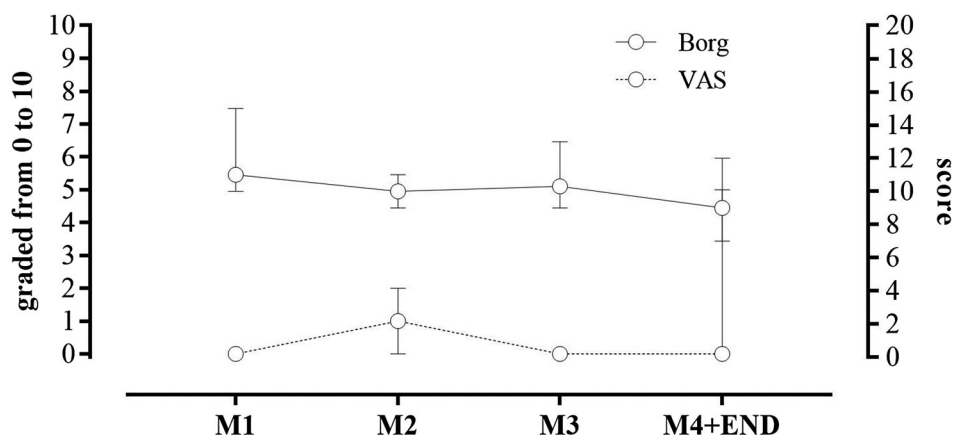
## Findings

Tolerance indicators (Table 2).

## Physical feasibility

The bicycle seat was covered with a VICAIR®-type pressure relief cushion. The legs were protected by foam gaiters in leggings.

No osteoarticular, cutaneous, or cardiorespiratory morbidity was noted. The systolic and diastolic blood pressure and the pulse rate measured 1 minute after the end of electrostimulation in each of the weekly sessions never exceeded a mean  $154 \text{ mmHg} \pm 15$  (R: 135–193),  $95 \text{ mmHg} \pm 8$  (R: 78–109) and  $76 \text{ bpm} \pm 8$  (R: 61–92), respectively. At 5-minute recovery, the values were as follows:  $144 \text{ mmHg} \pm 12$  (R: 112–157),  $92 \text{ mmHg} \pm 10$  (R: 70–106) and  $69 \text{ bpm} \pm 10$  (R: 49–87), respectively (Fig 2). Nociceptive pain in the neck and back manifested episodically. The weekly perceived



**Figure 3** Perceived effort represented by superimposed points graph linking points in time with data grouped by variables (legend). X axis presents the set of repeated measures recorded weekly during the first (M1), second (M2), third (M3) and fourth (M4) months before competition including the records in the end of training added in the M4 time-point (M4 + END). The Borg scale (score) is linked to right Y axis whereas the visual analogical scale (VAS) graded from 0 to 10 is linked to left Y axis. No significant difference ( $p > 0.05$ ) was found for the variables.

**Table 3** Changes in muscle parameters, in body composition and in bone mineral density (BMD).

				START	M1	M2	M3	M4	END	
Spasticity*	Adductors R			1	2	2	1	2	3	
	Adductors L			1	2	2	2	2	3	
	Quadriceps R			0	0	0	0	1	1	
	Quadriceps L			0	0	0	0	1	1	
	Hamstrings R			1	2	1	1	1	2	
	Hamstrings L			1	1	1	0	1	2	
	Triceps surae R			2	2	1	2	2	3	
	Triceps surae L			2	2	3	1	2	3	
Spasms in lower limbs**				3	2	4	4	2	3	
Thigh circumference (cm) <sup>‡</sup>	At the upper edge of the patella			R	39	39	39	39	39	
				L	39	38	39	39	39	
	+ 10 cm from the upper edge of the patella			R	42	42	43	42	43	
				L	42	41	43	42	43	
	+ 20 cm from the upper edge of the patella			R	49	50	49	49	48	
				L	46	47	48	47	46	
Body Composition Dual-Energy X-Ray absorptiometry (DXA)	Fat mass (gr)	Arm	L	791					630	
			R	702					614	
		Trunk Leg		7941					6252	
			L	2776					3055	
	Lean mass (gr)		R	3046					3253	
				15256					13804	
		Arm	L	3398					3287	
			R	3675					3613	
		Trunk Leg		26806					26466	
			L	7473					7226	
			R	7355					7678	
				48707					48269	
	% Fat mass	Arm	L	18					15	
			R	15					14	
		Trunk Leg		23					19	
			L	27					29	
			R	29					29	
				23					22	
		Bone Mineral Density (gr/cm <sup>2</sup> ) Dual-Energy X-Ray absorptiometry (DXA)	Total body Lumbar spine		0.991					1.076
					1.355					1.186
Pelvis Leg			0.917					0.935		
	L		0.884					0.926		
	R		0.889					0.902		
			0.888					0.89		
Subtotal			0.888					0.89		
			0.888					0.89		
T score Z-score			-1.6					-1.5		
			-1.4 / 89%					-1.2 / 60%		

M, Month; L, left; R, right; \*Modified Ashworth Scale from 0 to 4.

\*\*Penn Spasm Frequency Scale from 0 to 4; <sup>‡</sup>assessed while the subject was lying in bed.

effort rating fluctuated over the first 6 months but tended to decline in the second period of training. No significant difference ( $p > 0.05$ ) was found for both variables (Fig 3).

### Psychological feasibility

The acceptability of the training constraints increased steadily over the months. The initial level of satisfaction was high, around 8/10, but fell at points to 6/10 before returning to 8/10, and peaked at 10/10 the day after the competition.

### Functional feasibility

Training began on the stationary Berkelbike Pro® and, in week 19 when JP switched to the competition ICE

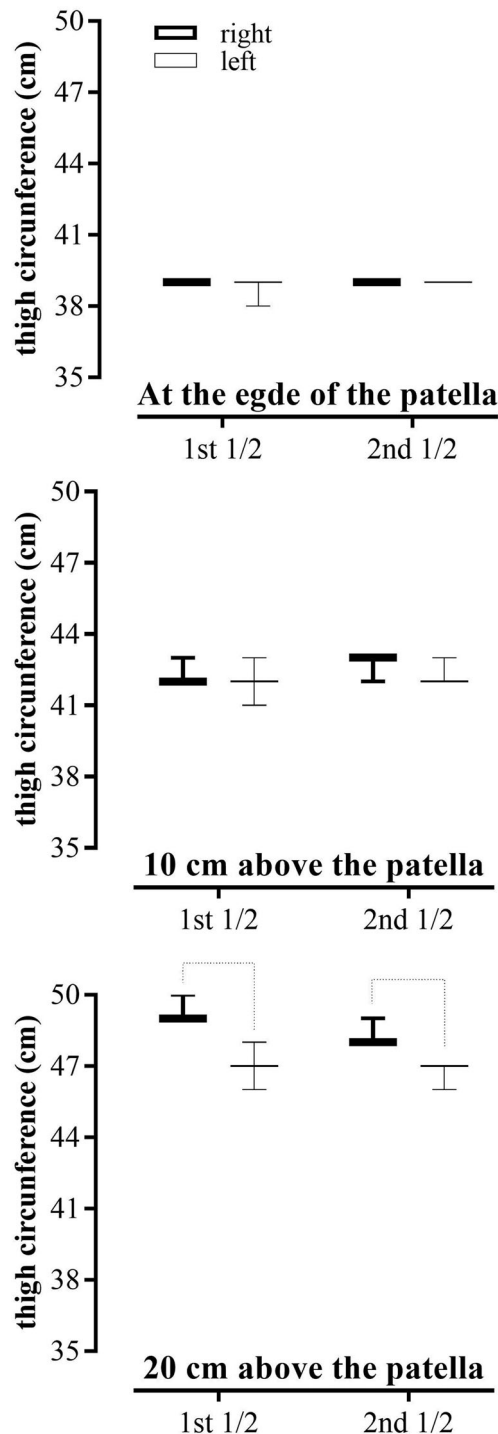
Trike Adventure, his pedaling duration increased dramatically (from 415 sec to 1549 sec). In parallel, non-stationary trials on this same bicycle showed an increase in the pedaling time in week 17 coinciding with three technical changes: switching the bike to fixed-gear (with pedals permanently coupled to the rear wheel), stimulation distributed over the different quadriceps heads, and the determining effect of changing the rolling surface for better ground adhesion. After the Cybathlon competition, JP interrupted his cycle training but continued with two FES sessions per week at home between weeks 22 and 29. At the end of this interruption, he had maintained an optimal endurance level and pedaled for 13 minutes and 44 seconds.

**Table 4** Changes in cardiorespiratory parameters.

Hand-held Ergometer Exercise test			Before training program					End of training program				
			30/05/2016					10/10/2016				
			Duration of level	HR (/min)	Max Blood pressure	Respiratory quotient (VCO <sub>2</sub> /VO <sub>2</sub> )	VO <sub>2</sub> max (ml/kg/min)	Duration of level	HR (/min)	Max Blood pressure	Respiratory quotient (VCO <sub>2</sub> /VO <sub>2</sub> )	VO <sub>2</sub> max (ml/kg/min)
Pre-test		0	08:40	60	109/81	1.23	19.5	01:35	86	120/60	nc	18.4
Workload	Level 1	20	01:00	86				01:00	112			
	Level 2	30	01:00	92				01:00	120			
	Level 3	40	01:00	103				01:00	131			
	Level 4	50	01:00	110				01:00	137			
	Level 5	60	01:00	122				01:00	153			
	Level 6	70	01:00	141				01:00	162			
	Level 7	80	01:00	155				01:00	171			
	Level 8	90	01:00	MHR = 166 [96% of the estimated MHR (173 beats/min)]	130/74			01:00	MHR = 179 [103% of the estimated MHR (173 beats/min)]	140/90		
Cessation due to exhaustion												
Recovery		11 :04					09:14	116	105/70			

MHR, maximum heart rate; nc, unknown.





**Figure 4** Thigh circumference took on the distal (at the edge of the patella), medial (10 cm above the edge of the patella) and proximal (20 cm above the edge of the patella) thirds and recorded by lower limbs (right and left) assessed by the set of repeated monthly records on the first (1<sup>st</sup> 1/2) and second (2<sup>nd</sup> 1/2) halves of the training. Significant differences between limbs were detected ( $p < 0.05$ ) for both phases of the training (indicated by pointed lines).

### Impact indicators

#### Physical impact

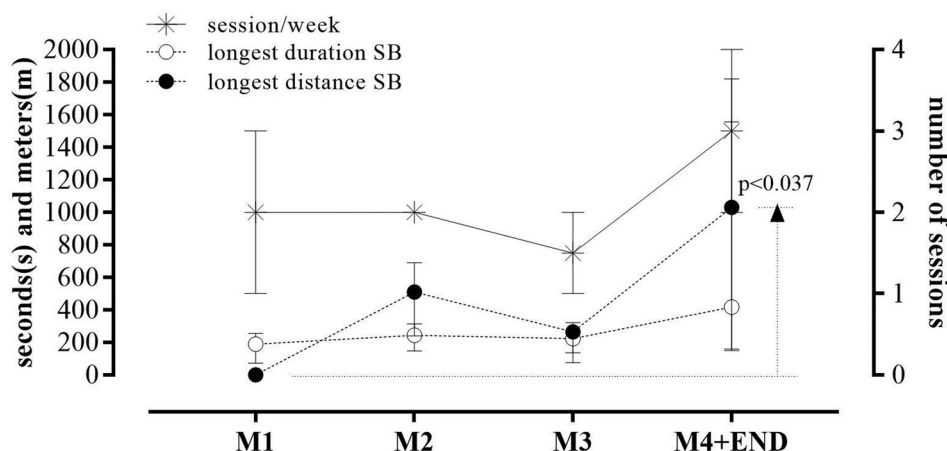
We evaluated five factors: spasticity, thigh circumference, body mass, BMD (Table 3) and cardiorespiratory function (Table 4). The maximum load of 90 W was maintained for 1 minute at the beginning but also the day after training. The maximum heart rate (MHR) changed from 96 to 103% of the mean value. VO<sub>2</sub>max showed a small drop (from 19.5 to 18.4 ml/kg/min) but the final measure of the VO<sub>2</sub>max may have been underestimated in the final phase. Spasticity, which was evaluated using the Modified Aschworth Scale (MAS) before the start of cycle training and then once a month until competition, did not improve significantly ( $p < 0.05$ ). JP nevertheless reported an immediate, sustained and appreciable decrease in spasms for a few hours after each pedaling session. The body mass at the beginning and the end of the cycle training suggested an overall decrease in body fat in the arms and trunk – that is, above the lesion level. BMD showed a very little change, with the T-score progressing from -1.6 to -1.5. The increase in BMD mainly concerned the pelvis and leg bones. None of these changes were statistically significant. Only thigh circumference increased significantly and JP noted a change in the shape of his thighs and said that he felt more at ease wearing short pants or shorts (Fig 4).

**Table 5** Change in indicators of self-esteem and quality of life.

		START	M1	M2	M3	M4	END
Evaluation of quality of life SF36*							
Physical score	Physical functioning	25					35
	Physical role functioning	100					100
	Bodily pain	80					90
	General health perception	67					88
Mental score	Vitality	60					70
	Social role functioning	50					88
	Emotional role functioning	100					100
	Mental health	60					84
Evaluation of self-esteem (Rosenberg) /40**		36	40	39	39	39	40

\*Short Form Health Survey (8 dimensions of quality of life); \*\*10 items scored from 1 to 4.





**Figure 5** Protocol's progress represented by superimposed points graph linking points in time with data grouped by variables (legend). X axis presents the set of repeated measures recorded weekly during the first (M1), second (M2), third (M3) and fourth (M4) months before competition including the records in the end of training added in the M4 time-point (M4 + END). The number of session per week (session/week) is linked to right Y axis whereas the longest duration and distance performed on the stationary bike (SB) are linked to left Y axis. The arrow bounded by pointed lines indicates a significant difference ( $p < 0.05$ ) between M1 and M4 + END for the longest distance performed on the SB.

### Psychological impact

The subject's perceived quality of life was reflected by both the Physical and Mental Component scores on the SF36 and the Rosenberg Self-Esteem Scale. Both have shown good reliability, validity and good internal consistency in patients with SCI.<sup>11,12</sup> All dimensions but physical and emotional functioning showed significant improvement of at least 10%. The score on the Rosenberg Self-Esteem Scale was 36/40 on inclusion but rapidly improved and remained at a level of 39 or 40/40 up to the competition (Table 5).

### Functional impact

The longest distances covered on the stationary and road-going recumbent bike were recorded every week, as well as performance at the Cybathlon competition (Fig 5). The functional impact was assessed in two situations:

- **Speed during Cybathlon 2016** at week 22. The subject reached the objective of covering 750 m in under 8 minutes. He covered this distance in 467 s at an average speed of 5.80 km/hr and a maximal speed of 6.14 km/hr. The pedaling was smooth and regular as evidenced by the low variability in his speed.
- **Endurance** at week 29. Although JP interrupted his cycle training between weeks 22 and 29, he continued home FES and showed a significant improvement over his previous performances by covering in one go a 1,080-m run in 13 minutes and 44 seconds for a mean speed of 4.6 km/hr and a maximal speed of 9.4 km/hr.

### Conclusion

The great difference between the FES-driven recumbent bike and the cycle ergometer is the need to control the stimulation pattern of the bike with regard to the terrain — trajectories (e.g., turns), surfaces, topography — and the cycles of crank rotation.<sup>6</sup> The literature on the physiological and functional benefits of FES-assisted recumbent bike pedaling is sparse. One study showed strong evidence that FES-assisted pedaling improved bone mineral density (BMD) in children 5–13 years old.<sup>6</sup> Many other studies have demonstrated a similar positive effect on bone demineralization, as well as on muscle atrophy, cardiovascular adaptations and carbohydrate metabolism.<sup>5,7,13–15</sup> Most often, these studies have dealt with stationary bikes or ergometers, and it should be noted that overall the methods did not produce results that fully matched the expectations. The only controlled study comparing a cycling + FES group of patients with paraplegia and another group of patients with paraplegia in functional rehabilitation was performed using an ergometer.<sup>8</sup> The strength of this study was its finding of significant improvement in body composition, FES-induced muscle strength, quality of life, intestinal transit, and LDL cholesterol. Muscle volume, BMD and many other parameters were not altered. In another hybrid approach, the combination of arm cycling and FES-assisted pedaling, like on rowing in order to work both upper and lower limbs, did not offer greater benefits than foot pedaling under electrostimulation alone.<sup>16,17</sup>

The present case report is the only one in the literature that provides a longitudinal approach of the effects of FES cycling training in a person with paraplegia. He received training and follow-up for a period of 12 months leading up to a competition. This study unveils quantitative measures that suggest a significant margin of improvement of the distance covered with a recumbent bike. It also highlights that an instrumented recumbent cycle adapted from a commercially device for non-disabled individuals can be financially accessible and available for a competition training. As the combination of a fixed-gear bike with a sequential muscular stimulation contributed, from week 17 onward to the improvement of the performances overtime, we can advance the hypothesis that training in a shorter time period — 3 to 4 months — is likely to offer the same margin of progress and that the indicators used for the assessment may be meaningful in a larger sample of patients. There is no consensus about the duration of FES required to achieve impact on BMD. Belanger *et al* showed, after FES training of the quadriceps, that patients with SCI (C5 to T5) had recovered nearly 30% of the bone lost, compared with the controls. Duration and frequency of training were 1 hour a day, 5 days a week, for 24 weeks. However, quadriceps was stimulated to contract against an isokinetic load (resisted). This resistance showed its added value by comparison with the contralateral quadriceps stimulated without any resistance.<sup>18</sup>

With regard to the experience in itself, several important conclusions can be drawn:

- a) A person who has had paraplegia for many years with a high lesion level can undertake this type of challenge provided exclusion criteria are abided by -body mass index  $\geq 30$ , no pressure ulcer, neurogenic paraosteoarthritis, thrombophlebitis, muscle disease, cardiovascular disease, T-score value of Bone Mineral Density  $< -2.5$ , hip or knee arthroplasty, epilepsy, hypotension, lower limb fracture within the past 12 months, a pacemaker or other implant, and pregnancy;
- b) The quadriceps play a decisive role in driving the cranks and the hamstrings are important in stabilizing the knee. However, the impossibility to stimulate the gluteal muscles did not appear to be disadvantageous a posteriori.
- c) This type of training is without danger if safety precautions are respected -skin protection and interruption of training in case of upsurge of spasticity with a risk of fracture.
- d) The training itself, the challenge of participating in a competition, and the sheer pleasure of cycling outdoors without attracting stigmatizing attention all

had a powerful impact on JP's self-esteem and perceived quality of life.

- e) The degree of progress we observed justifies a multicenter, controlled and randomized study with the main objective being 75% improvement of the duration of pedaling and of the distance covered on a bike, over a 4-month training period.

Working hypotheses to improve endurance by improving the efficiency and "profitability" of pedaling and by reducing fatigue are raised as potential perspectives for a technological development:

1. Give the ankle joint greater play and stimulate the gastrocnemius to strengthen the push on the pedals during knee extension, in order to share the workload with the quadriceps.
2. Define a real stimulation strategy: during the pedaling cycle, decompose and individualize stimulation when several heads of the same muscle are involved, and associate the gastrocnemii and/or glutei to confirm or invalidate their contribution.
3. Develop the fixed-gear principle and have a range of pinions with increasingly larger diameters for adaptation as training continues and progress is made.
4. When muscle fatigue causes a drop in the pedaling cadence, offer the option of FES-assistance from the bicycle until recovery.

#### Manufacturers' information

*DXA Hologic 4500 A*: Hologic, Inc., Bedford, MA, USA

*Berkelbike Pro® & Berkelbike FES box®*: Berkelbike BV, Sint-Michielsgestel. The Netherlands

*Ice Trike Adventure 26®*: Tregoniggle Industrial Estate, Cornwall, UK

*Vicair®*: Vicair BV, Ax Wormer. The Netherlands

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#### Disclaimer statements

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**Appendix Score of acceptability.**

	Completely agree	Somewhat agree	Neither agree nor disagree	Somewhat disagree	Completely disagree
It is hard to fix the electrodes on my own.	1	2	3	4	5
FES training for 30 minutes per day is too restrictive.	1	2	3	4	5
Learning to use and using the electrotherapeutic device on my own is difficult.	1	2	3	4	5
I can do the complete training session (FES and recumbent bike training) on my own.	5	4	3	2	1
I am comfortable enough on the recumbent bike to last for the entire training session.	5	4	3	2	1
Transfer to the recumbent bike is easy.	5	4	3	2	1
I have noticed an improvement in my physical capacities (supra- and sublesional) over the course of the training sessions.	5	4	3	2	1
I have noticed physical changes since the start of using the CEFAR.	5	4	3	2	1
Training (FES + recumbent bike) is quite fatiguing.	1	2	3	4	5
I enjoy FES-assisted training on the recumbent bike.	5	4	3	2	1
I feel good seeing myself improve in an athletic activity.	5	4	3	2	1
Having athletic competition as my objective has motivated me and helped me to commit to training.	5	4	3	2	1
FES-assisted recumbent cycling is personally satisfying.	5	4	3	2	1
TOTAL POINTS: Maximal score: 65; minimal: 13					